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The effectiveness of post-deployment screening for mental disorders and impact of tailored advice about help-seeking in the UK military: A cluster randomised controlled trial

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Background The effectiveness of post-deployment screening for mental disorders has never been assessed in a randomised controlled trial (RCT). The primary aim of this study was to assess whether post-deployment screening for posttraumatic stress disorder (PTSD), depression, anxiety and/or alcohol misuse was effective. Screening was defined as the presumptive identification of unrecognised disorder using tests to distinguish those who probably have a disorder from those who probably do not so that those with a probable disorder can be referred for diagnosis and treatment. Effectiveness was assessed by the odds ratios at follow up for the main outcomes between those receiving tailored advice and those receiving only general advice, and the secondary aim was to assess whether tailored advice following assessment increased help-seeking behaviour in those with a probable mental disorder.

Methods The study was a cluster RCT conducted among military personnel following deployment to Afghanistan. Initial assessment took place 6 to 12 weeks post-deployment, follow-up measures were obtained 10 to 24 months later. Follow-up measures were PTSD checklist civilian version, Patient Health Questionnaire-9, Generalized Anxiety Disorder questionnaire, Alcohol Use Disorder Identification Test (AUDIT) and self-reported help-seeking from clinical and welfare providers comparing those receiving tailored advice and those receiving only general advice.

Findings 274 platoons (6,350 subjects) were randomly allocated to the screening arm and 160 platoons (3,840 subjects) to the control arm. 5,577 (87·8%) received the screening, of which 3,996 (62·9%) completed follow-up, while 3,149 (82·0%), were controls of which 2,369 (61·7%) completed follow-up. 1,958 (35·1%) of those in the screening arm declined to see the tailored advice; but those with PTSD, anxiety or depression (approximately 83%) were more likely to view the advice. At follow-up, there were no significant differences for PTSD (OR 0·92, 95% CI 0·75- 1·14), depression and/or anxiety (OR 0·91, 95% CI 0·71- 1·16), alcohol misuse (OR 0·88, 95% CI 0·73- 1·06) or seeking support for mental disorders (OR 0·92, 95% CI 0·78- 1·08).

Interpretation Post-deployment screening for mental disorders based on tailored advice was not effective at reducing prevalence of mental health disorders, nor did it increase help-seeking rates. Countries that have implemented post-deployment screening programmes for mental disorders should consider monitoring the outcomes of their programmes.

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The United Kingdom (UK) deployed in excess of 220,550 personnel to the Afghanistan and Iraq conflicts between 2001 and 31 March 2014,[1] approximately 37% of whom deployed more than once.[2] Fatalities and seriously injured personnel from those conflicts amounted to 632 and 838 respectively,[3, 4] similar rates (but not absolute numbers) to those experienced by United States forces. The intensity of operations and the high proportion of the total strength of the UK Armed Forces (UK AF) that participated in these conflicts created an expectation that the conflict would have a substantial impact on the mental health of UK service personnel. Although higher rates were observed in those in direct combat roles, the prevalence of PTSD, psychological distress and alcohol misuse among regular UK personnel deployed to Iraq and Afghanistan was four percent, 20% and 16% respectively,[5] not dissimilar to rates found among those who did not deploy to Iraq and/or Afghanistan.[5, 6] But even though the rates are not as high as some anticipated, the absolute numbers are still substantial. Mental health screening is one way to address these problems. Several countries have done so implementing a mental health screening programme on return from deployment, the most sensible time to do so.

Screening uses relatively simple tests which are not intended to be diagnostic to distinguish between those who may or may not have a condition in order to provide early diagnosis and treatment for those who may have a disorder so that longer-term negative health consequences can be mitigated. The US military has implemented a post-deployment screening programme for mental disorders with repeated assessments in the 30 months following the end of deployment.[7] Canada, Australia and the Netherlands also utilise post-deployment screening procedures for mental disorders. [8, 9] The drive to implement mental health screening arises from findings that at least half of military personnel with probable mental disorder do not seek help,[10,11] that many seek help too late,[12] that chronicity is associated with slower recovery,[7] that screening may help to overcome stigma associated with mental disorder,[13] and finally, that government supported screening programmes demonstrate a commitment to providing preventive services to military personnel returning from deployment.[14] However, to date, no randomised control trials (RCTs) have assessed the effectiveness

of screening or its impact of on help-seeking behaviour. As the UK has not mandated such a programme we had the opportunity to conduct a RCT of screening, which would not have been possible in countries where screening was already national policy, in part because of the potential ethical and public opinion impact of discontinuing an established programme. To date, only observational studies have measured the impact of post-deployment screening; such studies showed that only a subset of those screening positive for mental disorders sought and received an adequate number of therapy or treatment sessions [15]. Studies lacking a randomisation and control element cannot answer the key questions regarding the effectiveness or its impact on help-seeking.

The primary aim of this study was to assess whether offering tailored help-seeking advice following assessment for possible PTSD, depression, anxiety and alcohol misuse was effective in reducing prevalence. The secondary aims were whether post-deployment screening followed by tailored advice to seek help from welfare or medical sources for those with mental health symptoms would modify help-seeking behaviour and/or medication usage. We also assessed screening for PTSD (and other mental health problems) reduces the prevalence of post-concussion symptoms (PCS) following mild traumatic brain injury (mTBI) and finally whether there was a difference in subjective functional impairment between the screening and the control arm participants.

Methods

Trial design, participants and procedures

A cluster randomised controlled trial (cRCT) was designed. We named it the Post Operational Screening Trial, or POST for short (registered number ISRCTN19965528). Following seven months preparation and piloting, the initial assessment of personnel occurred between November 2011 and February 2013. Follow-up took place between November 2012 and October 2014. We followed the latest Consolidated Standards of Reporting Trial (CONSORT) guidelines available at the time of study design. The cluster unit of randomisation was the platoon (usually comprising 15 to 35 service personnel). There were two arms: the screening group, which was offered tailored help-seeking

advice following an offline computerised self-administered assessment for mental disorders, based upon the test results for PTSD, depression, anxiety and alcohol misuse; and a control group which completed the same self-administered questionnaire as the intervention group, but received only general mental health advice. Only platoon members who had recently returned from deployment in Afghanistan at the time of assessment were included. The exclusions were members of platoons who did not deploy, those who deployed but moved to another location before randomisation, reserve personnel (mobilised specifically for the operation) and platoons which were formed specifically for deployment and had dispersed upon return home.

Participants received written and oral explanations about the study on the day of baseline assessment and were free to withdraw consent at any time during the study. Consent to follow up was requested from all participants. We used Zelen's design,[16] which required that each individual in the screening group should give positive consent to see the tailored advice related to their mental health status, but not those receiving general advice in the control group. This was deemed necessary by an Ethics Committee who wanted participants in the screening arm to have the option of whether or not to receive tailored advice. Zelen's design allows for the unwillingness to receive personal advice or management without introducing bias or attrition that would arise by requesting consent prior to assessment in the screening arm, especially when a cluster design is used. It also allows for carrying out a sensitivity analysis on the possible effect of unwillingness to receive tailored advice. Only Royal Marines and Army personnel were included in this study. The advice, specific or general, appeared at the end of the mental ill-health screening procedure, and a letter reiterating the advice was posted to everyone assessed at baseline in an envelope marked "Private and Confidential" within two weeks of the initial assessment (see letters in supplementary materials). Participants who chose not to see their tailored advice at the time of the assessment were invited to contact us if they had changed their minds and wanted to see the advice.

The baseline assessment was carried out between 6 and 12 weeks post-deployment. This was chosen to avoid interfering with immediate post-deployment leave and to minimise dispersion of personnel from the deploying platoons. The reassessment took place between 10 and 24 months after the initial assessment; but 3·5% of participants completed the follow-up assessment more than two years after initial assessment. Time variation in the completion of the assessment between the two arms of the study was significant due to change in randomisation ratio (see below), but adjusted for in the analysis as explained in the statistical analysis section. Three modes of administration of identical questionnaires were used in the follow-up assessment: an offline questionnaire on a laptop as used in the baseline assessment for those who were still in their original platoons and in their base on the day of the follow-up visit; an online version uploaded to a secure server; and a hard copy questionnaire that was used for those who did not have access to the electronic versions or were unwilling to use them. This multi-method approach was necessary because a large percentage of participants had changed platoons, were unavailable on the day of the follow-up visit to the base, or had left the Armed Forces (AF) between assessments. Members of the selected platoon were invited to participate regardless of the length of deployment and included those who returned early due to injury or illness. All those previously randomised were included in the follow-up stage regardless of whether they had participated in the initial assessment or not and including those who had left the UK AF for any reason since screening.

Masking procedure

The Mental Health and Neurosciences Clinical Trial Unit (MH&N CTU) at King's College London carried out the randomisation. They had no knowledge of the platoons other than the numeric identification provided by the fieldworkers preparing the visits to the bases at the time of randomisation. 45 laptops were preloaded with the screening (tailored advice) and control (general advice) questionnaires. Fieldworkers knew whether the platoon in the room would be allocated to the intervention or control groups, as they had to set up the appropriate offline version of the

questionnaire for each group. The person analysing the data (HB) but not the statistician (MK) or principal investigators knew the allocation of platoons at the time of analysis.

Measures at baseline

First stage-assessment

The initial offline assessment was a short two-stage questionnaire which included the primary outcome measures of posttraumatic stress disorder (PTSD), depression, generalised anxiety disorder (GAD) and alcohol misuse. We have previously reported that the two-stage questionnaire reduced resource burden without substantial loss of sensitivity for PTSD.[17] For the secondary outcomes we included a question from the short form-36 (SF-36) to assess functional impairment[18] and a modified version of the Brief Traumatic Brain Injury Screening schedule exploring possible symptoms associated with injury; these symptoms were losing consciousness, being dazed or confused, not remembering the injury and symptoms of concussion (e.g. headache and dizziness).[19] Sex, age, rank and service arm were also recorded. The four item primary care PTSD (PC-PTSD) test (score range zero to 4)[20] was used in the first stage and if two or more items were endorsed, respondents were directed to complete the PTSD checklist civilian version (PCL-C).[21] The first two items (mood and anhedonia) in the Patient Health Questionnaire (PHQ-9) were used in the first stage; endorsing a symptom frequency of “more than half the days” or “nearly every day” for at least one item triggered the administration of the full PHQ-9.[22] The first two items of the GAD scale were used for the first stage; if the participant scored three or more out of a total score of six, the full GAD scale was administered.[23] Alcohol use was assessed using the first two items of the Alcohol Use Disorder Identification Test (AUDIT) modified to allow for higher alcohol consumption as extra categories.[24] Any person scoring eight or more, based on a frequency category from zero to four or more times a week and an eight category scale of increasing consumption, was directed to complete the full AUDIT questionnaire.

Second stage assessment

The tailored advice consisted of one of three recommendations: First to visit a unit welfare officer (UWO) (padre, welfare staff or commander responsible for personnel welfare); second to visit to a medical officer (MO) or thirdly, that no professional support was required (an example of a tailored advice letter is shown in the supplementary materials). The general advice stated that there were many ways to get help if needed from sources such as colleagues, leaders, padres, welfare staff or medical centres (an example of the letter of general advice is given in the supplementary materials). Figure 1 provides the decision pathways to seek either primary care, welfare services or if no support was recommended. For the PCL-C (range 17-85) a score of 40-49 prompted advice to see an UWO and a score of 50 or more to consult a medical officer (MO); for the PHQ-9 (range 0- 9) endorsing three to five symptoms occurring more than half the days prompted advice to visit a UWO and six or more an MO; for the GAD (range 0- 21) a score of 10-14 prompted advice to visit a UWO and 15 or more to visit a MO. For the AUDIT total score (range 0- 40) a score of 20 or more generated advice to visit a UWO, for alcohol-related harm (range 0- 16) a score of 10 or more prompted advice to visit a MO, as did a score of five or more on the dependence scale (range 0-12). If a participant was a case for more than one outcome, the tailored advice was related to the more severe outcome. We used a threshold score of 40 for PTSD to minimise the false negative rate. This approach is consistent with the aim of screening to be a presumptive diagnosis only. It is also consistent with the distribution of most disorders that tend to be more common at lower levels of severity than at high levels of severity. This should not affect the results of the trial, as the comparisons between arms were carried out using the same threshold. In our study we recommended that those with a score of 40 to 49 visit a welfare officer instead of a medical officer. A welfare officer would be in position to advise and help service personnel whether is advisable to see a doctor and a mental health specialist. Our expectation was that a consultation with a UWO may be helpful for personnel experiencing fewer symptoms given that UWOs are able to offer general support, and to arrange an appointment with a

MO if necessary. They may also be able to raise any concerns within the confidential unit welfare committee where personnel causing concern are regularly discussed.

Follow-up assessment

The follow up assessment included full versions of the PCL-C, PHQ-9, GAD-7 and AUDIT. The thresholds for being classified as a possible case were the same as those used in the baseline assessment. The item from the SF-36 assessing the impact of physical or emotional problems upon work or social functioning was used as a binary outcome which compared functional impairment occurring "all the time" or "most of the time" with lower frequency endorsements.[18] Nine possible PCS were assessed; namely headache, dizziness, feeling tired or having low energy, trouble sleeping, irritability/outbursts of anger, double/blurred vision, forgetfulness, loss of concentration and ringing in the ears.[25] The follow-up assessment included questions about the use of medical and welfare services in the previous 12 months, including receipt of prescriptions for antidepressants and hypnotics. The 'Medical service providers' category included MOs, GPs, mental health nurses, psychologists, psychiatrists, other health services professionals (nurses, physiotherapists etc.), Accident and Emergency departments and military social workers (who work directly with military mental health professionals). The 'Welfare service' category included unit welfare officer/teams, military chaplains, trauma risk management (TRiM) personnel, online help sources, Service charities (such as the Royal British Legion, the Soldiers, Sailors, Airmen and Families Association and Combat Stress) and civilian social workers; the latter are included as welfare providers, rather than medical support, as they may not work directly with mental health services in the same way as military social workers who have a dedicated mental health role. A sub–category of mental health services was formed including psychiatrists, psychologists, mental health nurses, and military social workers. Questions on pharmaceutical usage requested medication name and duration of taking anti–depressants and/or sleeping tablets in the last 12 months. In addition, a section was provided with

free text fields for describing any other medications taken in the last 12 months; textual responses were re-categorised into the existing medication categories.

Sample size and randomisation

At the protocol stage, a sample size of 6,000 personnel recruited over two operational phases was required to detect a decrease of 20% in the prevalence of PTSD, depression or anxiety with a power of 80% at a 5% level applying an inflation factor due to clustering of one percent. However, during the first phase of data collection, approximately 50% of respondents chose not to see the tailored advice. The initial protocol was therefore modified to include a third operational deployment and the randomisation ratio between intervention and control groups was increased from 1:1 to 2:1 for the second and third deployments. Thus the total sample was increased to a minimum of 9,000 Service personnel estimated from platoon size. The modifications ensured that the sample size requirements were more than satisfied even at the lowest threshold of acceptability for the number agreeing to see the tailored advice. Randomisation was carried out on the day of baseline assessment by the MH&N CTU based on the list of platoons to be assessed, first selecting the companies (approximately 120 personnel) eligible for the study and the platoons (sub-groups of companies) stratified by headquarters (largely command and support roles) and fighting components (largely combat and combat support role). The rationale for such stratification was that there were more commissioned officers (COs) and senior non-commissioned officers (NCOs) in headquarter elements. Randomisation was carried out using stratified block randomisation with randomly varying block sizes of two and four. Figure 2 shows the structure of the study. The main analysis was carried out by intention to screen irrespective of whether or not the participant chose to see the tailored advice following the assessment.

Statistical analysis

Statistical analyses were performed using STATA 11·2 (Statistical Software Version 11. StataCorp LP, College Station, TX). The main outcomes were assessed as binary variables rather than continuous variables; as the great majority of participants had scores well below any meaningful threshold of possible mental disorder, classifying them as non-cases, the majority in the "screening" arm received advice indicating that no welfare or medical help was required. The analyses of effectiveness of screening and help-seeking behaviour were carried out taking into account clustering by platoons and controlling for Service type (Royal Marines or Army) as a fixed covariate. The adjustment was needed to account for the change from 1:1 distribution of participants between the intervention and control arms in the first deployment to a distribution of 2:1 in subsequent deployments, as Royal Marines formed the majority of personnel on the first tour. Potential risk of bias in the estimated screening effect due to missing data (including missing due to incomplete questionnaire, missing outcome data at baseline and missing data due to non-response at follow-up) was handled under missing at random assumption by making additional adjustments for rank, age and date of deployment which were found to be associated with missingness or non-response; these adjustments also removed the apparent difference in response time between intervention arms, which was primarily a consequence of the change in sampling strategy between first and subsequent waves. We performed intention to treat analysis of available data irrespective of whether or not the participant chose to see the tailored advice following the assessment, using random effects logistic regression models implemented via the STATA command “xtmelogit”, with platoon as the clustering variable in unadjusted analysis with further adjustment carried out as described above. We performed analyses adjusting for covariates only and then performing additional adjustment for any mental health condition at baseline. There were 24 incomplete questionnaires for PCL-C, 35 for PHQ-9, 34 for GAD and 33 for AUDIT. We performed linear mixed model analyses without any imputation of missing observations, which is appropriate under the missing at random assumption of missing outcome data, provided covariates associated with missing data are accounted for and the analysis is performed via mixed models using the maximum likelihood method.[26] We compared personnel in

the two arms who reported at least three PCS at follow-up. We also compared any medical/welfare attendance and any use of the defined pharmaceutical categories with no medical/welfare attendance and no use of the defined pharmaceutical categories. When analysing the effect of viewing or not viewing the tailored advice, analysis was performed separately for those who would have been advised to seek help (whether medical or welfare) given their baseline scores on the various measures; we expected those who were advised that no help was necessary to differ from those advised to seek help. These analyses were performed for those advised to seek help for mental health reasons other than alcohol misuse alone, and were then repeated including alcohol, as serving personnel are is less receptive to help–seeking advice regarding alcohol use.[11] The effect of the screening programme on total number of mental health–related visits was analysed using mixed–effects Poisson regression, with random effects at both cluster and observation level (to compensate for over-dispersion as most have zero visits).[27] We also carried out sensitivity analyses creating five imputation sets using multiple imputation by chain equations, first for imputing missing covariates only, second imputing both covariates and baseline and follow-up outcomes for those responding at follow-up and thirdly imputing the 10,190 members in the study, irrespective of response at any stage. The sensitivity analysis showed similar results to those given in this paper. The reported analyses were decided a priori before seeing any results.

Role of the funding source:

The funders required that we submitted quarterly and annual reports informing them about the progress of the project for its duration. They also required for continuation of funding that we submitted an annual letter signed by the Ethics Committees which assured the funders that the study continued to fulfil ethical requirements. The funding body play no role in advising on the design of the study, data collection or interpretation of the results, and has not commented on the paper. The funders sent our protocol to reviewers when considering our project for funding and we modified the protocol following recommendations from the reviewers which were on points of detail.

Results

Response rates and characteristics of responders

A total of 434 platoons including 10,191 personnel were entered into the study, 274 (63·1%) in the intervention arm and 160 (36·9%) in the control arm (Figure 2). In the intervention group, 5,577 (87·8%) responded compared with 3,149 (82·0%) of control group participants.

Baseline participation was higher for tours 2 and 3 than for tour 1, but the participation rate was lower for those in headquarters platoons, the Royal Marines, and for NCOs and COs (Table 1). Most Royal Marines were part of tour 1. The response rate at follow-up was 62·9% (n=3,996) using the total initial sample in the screening group as the denominator, or 66·5% (n=3,708) using those completing the initial assessment as the denominator, in the control group the numbers were 61·7% (n=2,369) and 67·6% (n=2,128) respectively (Figure 2). The response rate at follow-up was higher for those in headquarters platoons, the Royal Marines, NCOs and COs (Table 1). Baseline mental health outcomes were not associated with likelihood of response at follow-up. Age of participants was positively related to completion of the follow-up questionnaire. Overall those in the screening arm responded quicker (15·1 months) than those in the control arm (15·4 months); however, as previously noted there was a change in the ratio of intervention to control after the first tour but no difference within waves of data collection. Differences between periods of data collection are adjusted for as explained in the statistical analysis section. 61·2% in the control arm and 58·2% in the intervention arm used medical services (mainly MOs and GPs) (Table 2). 15·0% and 13·9% in the control and intervention arms respectively used welfare services, and 13·4% and 12·4% in the control and intervention arms respectively used mental health services.

Elected to see the tailored advice

3,619 (64·9%) in the screening group chose to see the advice provided after assessment (Table 3). Lower ranks, younger personnel and non-cases were less likely to request to see the tailored advice. Higher percentages of those reporting symptoms related to PTSD (83·1% vs. 64·0%), depression or

GAD (84·2% vs. 64·5%) and alcohol problems (75·0% vs. 63·9%) wanted to see the specific advice than those who were non-cases. The difference for mTBI in comparison to non-cases was not significant.

Effectiveness of tailored advice

The odds ratios (ORs) for any of the mental health outcomes were not significant between the screening and the control arms, though the prevalence rates were slightly lower in the screening arm for each disorder category (Table 4). The 95% confidence intervals (CI) were sufficiently narrow to conclude that for all outcomes the slight decrease of prevalence in the intervention group was unlikely to represent an impact of the intervention. Exclusion of those without baseline information and adjustment for outcome at baseline did not change the results. The assessment of PCS between the two arms of the trial in those with a possible mTBI at baseline was not significant, but the statistical power for inference of this analysis was low.

The effect of screening on help-seeking behaviour

There was no significant difference in accessing health providers between the trial arms (Table 5). No significant difference in mental healthcare usage was found despite this being the primary source of psychological help recommended by the intervention, and there were no differences in pharmaceutical usage between trial arms.

Sensitivity analysis of the impact of the intervention

Choosing to see the tailored advice was not associated with the lack of effectiveness of screening for any of the outcomes (Table 6). The two adjusted analyses, one excluding baseline outcomes and the other including baseline outcomes, were similar.

Among those who would not have been directed to seek help based on mental health outcomes at baseline, the OR of help–seeking in the intervention arm compared to the control arm was similar

irrespective of whether the individual chose to view the tailored advice or not (Table 7). Among those who would have been advised to seek help, those who chose not to view the tailored advice were less likely to seek help than those in the control arm, but the reverse was not observed; those who chose to see the tailored advice were no different on their rates of help-seeking from those in the control arm (Table 7). In terms of pharmaceuticals, there were no significant differences for antidepressants or sleeping tablets, irrespective of the form of advice that would have been received (Table 7).

Mental health status at follow-up was unrelated to screening and the largest group at follow up, excluding non-cases was composed of cases that had developed following initial assessment (supplementary Table 1). We stratified the two arms into four groups: not a case, remitted, persistent and new case. The rationale for this analysis was to verify if the lack of effectiveness of screening might have been due to the heterogeneity of evolution of the conditions in the analyses. None of the results became statistically significant in the stratified analyses.

Of those qualifying as probable mental health cases (PTSD, depression and/or anxiety) at baseline, 45 (35·7%) in the control arm and 69 (33·3%) in the intervention arm had sought help from a mental health provider in the last 12 months (OR 0·95, 95% CI 0·59-1·54, p=0·849). Of those qualifying as cases at follow–up, 105 (35·5%) of those in the control arm and 141 (28·7%) of those in the intervention arm had sought mental healthcare in the last 12 months (OR 0·82, 95% CI 0·59-1·14, p=0·241). Of those seeking help from mental health services in the previous 12 months, 69 (14·7%) in the screening arm and 45 (15·9%) in the control arm were cases of mental health disorder at baseline (OR 0.97, 95% CI 0·64-1·48, p = 0.899), and 141 (28·4%) in the intervention arm and 105 (33·0%) in the control arm were cases at follow–up (OR 0·87, 95% CI 0·60-1·25, p = 0·446). None of the differences between trial arms were significant. Mental health service help–seeking rates were consistently lower in those with alcohol misuse- 90 (18·2%) at baseline and 163 (21·7%) among cases at follow–up.

We carried out analysis based on continuous scales of the outcome variables to assess effectiveness of screening, but none of the assessments were significant (Supplementary Table 2).

As shown in the Tables 3, 4 and 5 there was no evidence that anxiety or stress were associated with the tailored advice. We did not assess whether the tools used in the study over-diagnosed mental disorders.

Discussion

The main finding of this cRCT is that screening for mental disorder in UK military personnel and the provision of tailored help-seeking advice between 6 and 12 weeks after return from deployment is ineffective in decreasing the prevalence of PTSD, depression, anxiety and alcohol misuse over a period of 10 to 24 months. This study also demonstrated that tailored help–seeking advice linked to the results of mental disorder screening procedures, including potential alcohol misuse, did not influence subsequent help–seeking behaviour. Approximately a third of the participants in the screening arm did not want to see the tailored advice offered on-screen following completion of the baseline assessment; this group was less likely to access healthcare. Those who chose to see the help-seeking advice did not seek help more frequently than personnel in the control arm. Those who reported symptoms of mental disorders were more interested in seeing their advice than those who did not.

This is the first RCT to assess the effectiveness of post-deployment mental disorder screening in the Armed Forces anywhere in the world. We found no evidence to support that informing someone that they were experiencing mental health disorder symptoms promoted help-seeking from mental healthcare providers. Only around a third of those with symptoms of mental disorder at baseline had sought help from a mental health provider in the 12 months during the follow–up period.

In the following discussion we refer mostly to the US literature because is the largest, best developed and most researched programme. We have previously demonstrated that pre-deployment screening in UK service personnel did not lead to an increase in seeking health care and

that the prediction of subsequent psychiatric morbidity including PTSD was modest.[28, 29] A US study indirectly suggested that screening did not promote help-seeking behaviour among personnel with mental disorders.[30] On the other hand a further US study has shown that pre-deployment review of those who are already being treated for a mental disorder may have an impact on the prevalence of PTSD in deployed US military personnel by either debarring them from deployment or by providing ongoing monitoring for those already receiving health-care.[31] In the UK AF pre-deployment review is already practiced in those already receiving treatment for mental disorders. Both of these are very different to post-deployment screening which seeks to identify personnel with a possible mental disorder who have not sought mental healthcare.

An unexpected finding in this study was that a third of the participants in the screening arm decided not to receive tailored advice about help-seeking based upon screening outcomes. This was more common in younger groups and among lower ranks, both of which are risk factors for mental disorders.[5] However, only 15% among those with a score indicative of a mental disorder declined to see the tailored advice, with the exception of alcohol misuse (25%). The lack of interest in viewing the tailored advice shown by some UK service personnel occurred despite the vast majority receiving a homecoming briefing upon leaving the operational area; the briefing detailed symptom recognition in oneself and others, and how to access potential sources of mental health support if required. The unwillingness to see the tailored advice might be due to lack of interest, mistrust of health services, fear of receiving bad news and a conviction that mental health issues are not personally relevant.[32, 33]

One of the criteria for introducing screening for a condition is that the natural history of the condition should be adequately understood. Screening may not work for PTSD in particular because of the diversity of trajectories of the condition over time,[34, 35] even over a short period.[36] Approximately half of those who were cases at the screening stage had remitted at follow-up and the majority who were cases at follow-up did not have symptoms at baseline, consistent with our

previous results on PTSD. [37] Thus persistent PTSD symptoms are characteristic of a minority in this and other populations and those with a tendency to chronicity are not distinguished from the rest in a screening programme.

In our study symptoms of mental disorder levels following intervention in the tailored advice group were marginally less frequent for all outcomes, but not significantly so compared to the control arm. One can speculate that this might suggest that screening could potentially be effective in settings with a higher prevalence of PTSD such as the US military,[10, 12, 30] but, of course caution is necessary when extrapolating from non-significant differences, especially in a trial as large as ours. The current US screening programme also differs from what was tested in this trial in a number of ways. For example, since 2012 the US screening programme includes several opportunities for assessment of personnel during the post-deployment period.[7] These were introduced after the start of this cRCT in 2011. The US screening programme for most of the duration of the Iraq and Afghanistan conflict assessed personnel between 90 and 180 days post-deployment, which would overlap with the 90 days post-deployment period upper limit used in this study. The US programme also requires a mandatory face-to-face interview with a trained professional who will review the screening results. This approach would increase the number of cases with a suspected mental disorder starting treatment, but it could also include a high percentage of service personnel with short duration PTSD who may not need treatment, and despite receiving face-to-face advice some individuals may be reluctant to follow the advice. There is also a risk that, knowing that they would have a face-to-face interview if a test suggested a possible mental disorder, personnel may be more inclined to modify responses to questions in the direction of better health. This is supported by a US report that a lack of anonymity in a questionnaire (which of course must be the case in a practical programme) markedly decreases the reported prevalence of PTSD and depression.[38] Our study tested both a version of the US programme in place before 2012 (but without the mandatory face-to-face interview), as well as the most likely way a UK screening programme would have been introduced, not least because there were not and still are not sufficient UK personnel or resources to employ so

many health professionals at an early stage. But even if such resources were to be made available in future, a doubtful prospect, we are sceptical of an approach that adds an element of compulsion to a screening programme as such an approach may not be well received for many reasons, including privacy, fears related to impeded career progression, reduced military professional standing and a desire to deal with the problem without external help.

We understand that others may argue that a more resource intensive screening programme including repeated assessments over time and face-to-face interviews following each assessment would give results different to those presented in this cRCT. This could only be confirmed in a new RCT, but in the absence of such we would point out that US studies have already shown that screening identifies far fewer personnel who subsequently seek help for mental disorders than other modalities such as primary care referral, chain of command directed referrals and self-referrals,[12, 15] and confirm that a large percentage of those identified by screening do not seek help.[11, 12] A recent US study has shown that 75% of those referred for further mental health reasons contacted health providers, but 40% subsequently attended only one or two therapy sessions.[15] In another study it has been shown that 60% of personnel either failed to begin treatment or subsequently received an inadequate course of treatment.[39]

A further point to consider is that there are only a limited number of studies assessing efficacy of psychotherapy and treatment among military personnel, most of them in ex-military personnel, and the effect sizes between studies vary from negligible to strong effects. [40] [41] Many of the studies carried out to assess the efficacy of psychotherapy in the management of PTSD in clinical settings have limitations because they are observational studies rather than RCTs, comparison groups with a group receiving psychotherapy are made up with patients in a waiting list or being treated as usual, or are RCTs designed to compare two types of psychotherapy not including a true control group or are not analysed as intention to treat.[42, 43] No RCTs has been carried out to assess the efficacy of management of the outcomes in this study in the UK military. Even if they were highly efficacious

there are several difficulties that need solving such as barriers to seeking care, patients' willingness to adhere to the recommended sessions of psychotherapy and services that are properly staffed and organized to cope with a screening programmes for mental disorders. However, it is worth mentioning that in our study tailored advice did not impact upon health-seeking behaviour.

We used a high threshold for defining alcohol misuse. The rationale was that the prevalence of alcohol misuse in the UK AF is high,[5] and those misusing alcohol are less likely to acknowledge functional impairment and a health problem unless they also have a mood disorder or PTSD.[11] Even with this increased threshold, alcohol misuse was a major contributor to mental disorder in our study.

We assessed mTBI at baseline, but we did not offer tailored advice related to this event. In most studies PTSD is strongly associated with mTBI.[36, 44] The contention was that if screening for PTSD and other mental disorders was effective it should also decrease the number of PCS symptoms in those with mTBI. However, the screening programme was not effective in reducing the prevalence of any of the mental health outcomes, so the likelihood of an effect of the programme upon PCS was low.

There was no evidence that anxiety or stress were associated with the tailored advice in our study. We did not assess whether the questionnaires used in the study over-diagnosed mental disorders or led to unnecessary investigations, but all measures have been comprehensively validated. We acknowledge that by choosing a high threshold for identifying alcohol misuse we may have given a false sense of security to service personnel with a hazardous drinking pattern or a high intake drinking problem,[24] but we were concerned not to give the impression that detecting alcohol misuse was the main purpose of this study.

We recognise that it is usually advisable in an RCT to address the cost-effectiveness issues of the screening programme. We expect to report on this issue separately, as we collected information on

the volume of service and cost of each of the welfare and health services in relation to the use of services reported by the trial participants.

Strengths and weaknesses

The key strengths of the trial are the high response at baseline, a good response rate at follow-up, the high fidelity of the intervention throughout the study and the lack of differential attrition for the two arms of the trial, 1,868 (33·5%) in the screening arm and 1,021 (32·4%) in the control arm. Contamination between arms is a potential problem in RCTs, but it is less likely to occur in this cRCT as the unit of randomisation was platoon not individual; also the screening arm received individually tailored advice which was unlikely to be helpful to participants in the control group. Lack of blinding is always a problem in any RCT studies, but the purpose of this intervention was to modify behaviour in the screening arm and it is unlikely that lack of blinding between those who received tailored advice and those who received general advice would have influenced their responses at the reassessment stage of the study, on average a year later than the tailored advice was given.

Anonymity is unachievable in any screening programme, as its aim is to identify individuals with a suspected mental disorder. Some researchers may criticise a study design in which individuals can opt not to see the tailored advice. However, in any RCT, consent must be given by participants to receive an intervention even if the intervention is seemingly not harmful. Zelen's design avoids selection bias by randomisation before consent. Our approach both minimised participation losses, and allowed us to account for unwillingness to receive tailored advice. Questions regarding help–seeking did not specify the problem for which help was sought. This was necessary in order to capture maximum information regarding mental health problems and sources of help, and for practical reasons, as those in the control group were given general information not mentioning possible diagnosis of any mental disorder. This does not affect the interpretation of the results, as this was a pragmatic trial in which the main purpose was to assess whether screening in the military would work in a real world context. We relied on self-report at follow-up to obtain data on use of

services and pharmaceuticals. We did not ask about what diagnosis might have been made by the providers, since it would have been inconsistent, preferring instead to base diagnosis from the self-reported assessments. It is possible that there may be recall bias at work, including misclassification of help sources, and also unwillingness to report or misremembering events, but there is no reason to suspect biased reporting between trial arms. The small number of medication users limits the statistical power to properly evaluate any differences. We had minor errors with the randomisation procedure whereby a small number of participants (less than 50) were assessed with a different platoon and received the wrong questionnaire schedule. These participants were included in the intention to treat arm for analysis. We made a mistake in the algorithm to identify cases of depression in the offline tool at baseline. We identified those with a score of six positive responses instead of five; as a consequence, 16 cases were directed to informal care when their PHQ-9 responses should have caused them to be directed to primary care.

Implications

This study does not support the introduction of post-deployment screening for mental disorders in the UK AF. Tailored advice offered in a post-deployment screening trial for mental disorders had no significant effect upon help-seeking behaviour and is ineffective. Possible explanations for the ineffectiveness of post-deployment screening may be related to a number of factors including the heterogeneity of evolution of mental disorders over time,[34, 36] possible lack of interest in engaging with services in a proportion of cases[15] and potential unwillingness to continue treatment among those who engage with services.[12, 15] Previous research further suggests that between one third and half of treated personnel may not demonstrate meaningful symptom improvement and that those who improve remain above thresholds following trauma therapy.[41] One possible alternative to screening might be to undertake case-finding by primary care staff along the lines of the US Program Re-Engineering of Primary Care Treatment in the military (RESPECT-Mil). RESPECT-Mil is a treatment model designed to screen, assess and treat active duty soldiers with depression and/or PTSD in

primary care. This approach follows a programme proven effective in civilians. However, a recent report provided unenthusiastic support for the RESPECT-Mil programme in terms of detection of new cases, willingness of service personnel to see health care providers and length of treatment for those who engaged with the care team.[45]

In conclusion, this study demonstrates that the provision of tailored advice regarding help-seeking for mental illness embedded in a post-deployment screening programme among UK military personnel is ineffective in promoting help-seeking behaviour and in reducing the prevalence of mental disorders. Given the lack of any substantial evidence for post-deployment screening to date, we suggest that new programmes should not be implemented unless new evidence emerges that contrasts with our results. Perhaps it would now be prudent to reassess the efficiency, effectiveness and potentially unintended consequences of existing programmes.

Author's contribution: RJR, HB, DP and NTF had full access to all study procedures and take responsibility for the integrity and the accuracy of the data analysis. Study concept, design and protocol drafting: RJR, NG, NTF and SW. Data acquisition: MC, KG, DP and RJR. Analysis and interpretation of data: RJR, HB, NTF, MK, MC, KG, DP, NJ, NG, SW. Drafting the manuscript: RJR and HB drafted the manuscript. Critical revision of the manuscript for important intellectual content: RJR, HB, NTF, MK, MC, KG, DP, NJ, NG, SW. Statistical supervision MK. Obtained Funding: RJR, NG, NTF and SW. Administrative, technical or material support: RJR, DP, MC and KG

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Table 1 Characteristics of participants at baseline and follow-up, including response rates according to arm of the study.

Variable		**Control arm (n = 3,840)**		**Intervention arm (n = 6,350)**		**OR of response at follow-up for control arm (reference is intervention)**
		Baseline: number (%) responding	Follow-up: number (%) responding	Baseline: number (%) responding	Follow-up: number (%) responding	
All		3,149 (82·0)	2,369 (61·7)	5,577 (87·8)	3,996 (62·9)	0.95 (0·87-1·03)
Sex	Male	3,073 (88·0)	2,263 (64·8)	5,401 (91·7)	3,816 (64·8)	1.00 (0·92-1·09)
	Female	75 (86·2)	58 (66·7)	176 (95·7)	124 (67·4)	0.97 (0·56-1·66)
Deployment	Tour 1	1,227 (69·1)	1,029 (57·9)	1,412 (72·1)	1,150 (58·7)	0.97 (0·85-1·10)
	Tour 2	978 (90·4)	719 (66·5)	2,076 (93·8)	1,464 (66·2)	1.01 (0·87-1·18)
	Tour 3	944 (96·2)	621 (63·3)	2,089 (95·9)	1,382 (63·5)	0.99 (0·85-1·16)
Platoon type	Headquarters (HQ)	417 (66·6)	374 (59·7)	781 (79·7)	662 (67·6)	0.71 (0·58-0·88)**
	Non-HQ platoons	2,732 (85·0)	1,995 (62·1)	4,796 (89·3)	3,334 (62·1)	1.00 (0·91-1·09)
Service	Army	2,615 (82·7)	1,945 (61·5)	4,920 (89·2)	3,462 (62·8)	0.95 (0·87-1·04)
	Royal Marines	534 (78·7)	424 (62·4)	657 (78·8)	534 (64·0)	0.93 (0·76-1·15)
Rank	Other rank	1,579 (86·5)	1,094 (59·9)	2,742 (90·8)	1,826 (60·5)	0.98 (0·87-1·10)
	NCO	1,409 (81·0)	1,098 (63·1)	2,541 (87·7)	1,866 (64·4)	0.94 (0·83-1·07)
	CO	161 (63·6)	176 (69·6)	298 (70·8)	303 (73·0)	0.84 (0·60-1·19)

Age	18-24	-	876 (64·9)	-	1,525 (62·5)	1.11 (0·97-1·28)
	25-29	-	624 (66·3)	-	1,059 (66·4)	0.99 (0·84-1·18)
	30-34	-	353 (71·3)	-	603 (69·4)	1.10 (0·86-1·40)
	35-39	-	197 (77·6)	-	356 (78·8)	0.93 (0·64-1.35)
	40+	-	73 (73·0)	-	153 (78·5)	0.74 (0·42-1·30)
Baseline PCL	Not a case	-	2,016 (67·5)	-	3,529 (66·4)	1.05 (0·96-1·16)
	Case	-	110 (67·9)	-	174 (68·5)	0.97 (0·64-1·48)
Baseline PHQ-9/GAD case	Not a case	-	2,081 (67·5)	-	3,614 (66·3)	1.05 (0·96-1·16)
	Case	-	45 (71·4)	-	89 (73·6)	0.90 (0·46-1·77)
Any MH baseline case	Not a case	-	2,000 (67·5)	-	3,496 (66·3)	1.06 (0·96-1·16)
	Case	-	126 (67·7)	-	207 (69·5)	0.92 (0·62-1·37)
Baseline AUDIT case	Not a case	-	1,952 (68·0)	-	3,381 (66·6)	1.06 (0·97-1·17)
	Case	-	174 (63·0)	-	322 (64·9)	0.92 (0·68-1·25)
Baseline	Not a case		2,088 (67.7)		3,632 (66.4)	1.06 (0.96- 1.16)
mTBI	Case without LOC		28 (66.7)		50 (72.5)	0.76 (0.33- 1.74)
	Case with LOC		10 (52.6)		21 (70.0)	0.48 (0.14- 1.57)

* $p < 0.05$

** $p < 0.01$

*** $p < 0.001$

PCL= posttraumatic stress disorder checklist civilian version; PHQ-9= Patient Health Questionnaire-9; GAD-7= Generalised Anxiety Disorder-7 Scale; AUDIT= Alcohol Use Disorder Identification Test; MH= any mental disorder except alcohol misuse; mTBI= mild traumatic brain injury, cases included those symptoms associated with injury but not loss of consciousness (LOC) and those with lack of consciousness separately

NCO= non-commissioned officers; CO= commissioned officers

Table 2 Help–seeking and demographic factors

Variable		**Control arm**					**Screening arm**				
		n	No. using any health service (%)	No. using medical services (%)	No. using welfare services (%)	No. using MH services (%)	n	No. using any health service (%)	No. using medical services (%)	No. using welfare services (%)	No. using MH services (%)
All		2,369	1,500 (63·3)	1,450 (61·2)	356 (15·0)	318 (13·4)	3,996	2,410 (60·3)	2,327 (58·2)	557 (13·9)	496 (12·4)
Sex	Male	2,263	1,420 (62·8)	1,374 (60·7)	336 (14·9)	295 (13·0)	3,816	2,276 (59·6)	2,196 (57·6)	527 (13·8)	472 (12·4)
	Female	58	43 (74·1)	42 (72·4)	11 (20·0)	14 (24·1)	124	95 (76·6)	93 (75·0)	22 (17·7)	20 (16·1)
Rank	Other rank	1,094	672 (61·4)	651 (59·5)	186 (17·0)	175 (16·0)	1,826	1,073 (58·8)	1,036 (56·7)	267 (14·6)	273 (15·0)
	NCO	1,098	688 (62·7)	663 (60·4)	148 (13·5)	123 (11·2)	1,866	1,136 (60·9)	1,097 (58·8)	254 (13·6)	207 (11·1)
	CO	176	139 (79·0)	135 (76·7)	22 (12·5)	19 (10·8)	303	200 (66·0)	193 (63·7)	36 (11·9)	16 (5·3)
Service	Army	1,945	1,233 (63·4)	1,192 (61·3)	304 (15·6)	286 (14·7)	3,462	2,102 (60·7)	2,033 (58·7)	491 (14·2)	440 (12·7)
	RM	424	267 (63·0)	258 (60·9)	52 (12·3)	32 (7·6)	534	308 (57·7)	294 (55·1)	66 (12·4)	56 (10·5)
Age	18–24	876	513 (58·6)	496 (56·6)	126 (14·4)	133 (15·2)	1,525	859 (56·3)	827 (54·2)	202 (13·3)	226 (14·8)
	25–29	624	400 (64·1)	387 (62·0)	96 (15·4)	78 (12·5)	1,059	649 (61·3)	633 (59·8)	146 (13·8)	123 (11·6)
	30–34	353	234 (66·3)	225 (63·7)	57 (16·2)	42 (11·9)	603	397 (65·8)	384 (63·7)	99 (16·4)	74 (12·3)
	35–39	197	130 (66·0)	126 (64·0)	30 (15·2)	23 (11·7)	356	209 (58·7)	200 (56·2)	42 (11·8)	30 (8·4)

40+	73	51 (69·9)	49 (67·1)	9 (12·3)	7 (9·6)	153	109 (71·2)	105 (68·6)	22 (14·4)	14 (9·2)

MH services= mental health services; NCO= non-commissioned officer; CO= commissioned officer; RM= Royal Marine

Table 3 Characteristics of those accepting to see the specific advice in the intervention (n= 5,551)

Variable		**Choosing to see advice (%)**	**OR (95% CI)**
All consenting to view advice		3,603 (64·9)	
Sex	Male	3,491 (65·0)	1
	Female	112 (63·6)	0·94 (0.69-1·29)
Rank	Other rank	1,661 (60·8)	1
	NCO	1,698 (67·3)	1·33 (1·19-1·49)***
	CO	244 (83·0)	3·15 (2·30-4·31)***
Age (years)	18-24	1,527 (62·3)	1
	25-29	1,045 (65·7)	1·16 (1·02-1·33)*
	30-34	594 (68·4)	1·31 (1·11-1·55)**
	35-39	304 (67·9)	1·29 (1·04-1·60)*
	40+	136 (70·1)	1·43 (1·04-1·96)*
Baseline PCL case (40+)	Not a case	3,393 (64·0)	1
	Case	210 (83·0)	2·74 (1·97-3·82)***

Baseline PHQ-9/GAD case	Not a case	3,502 (64·5)	1
	Case	101 (84·2)	2·93 (1·79-4·80)***
Any MH baseline case	Not a case	3,357 (63·9)	1
	Case	246 (82·8)	2·73 (2·01-3·70)***
Baseline AUDIT case	Not a case	3,233 (63·9)	1
	Case, no comorbidity	287 (74·0)	1·60 (1·27- 2·03)***
	Case, comorbidity PCL, PHQ-9 or GAD	83 (78·3)	2·04 (1·28- 3·24)**
Baseline mTBI	Not a case	3,534 (64.8)	1
	Case without LOC	47 (68.1)	1.16 (0.70- 1.93)
	Case with LOC	22 (73.3)	1.49 (0.66- 3.36)

*** $p < 0.001$

** $p < 0.01$

* $p < 0.05$

PCL= Posttraumatic stress disorder Checklist - Civilian Version; PHQ-9 = Patient Health Questionnaire-9; GAD-7= Generalised Anxiety Disorder-7 Scale; AUDIT= Alcohol Use Disorder Identification Test, MH= any mental disorder, excluding alcohol misuse; mTBI= mild traumatic brain injury, cases with lack of consciousness (LOC)and those with symptoms associated with injury but not loss of consciousness separately

Table 4: Mental health, alcohol misuse and functional impairment prevalence and odds ratios at follow-up between intervention and control arms

Outcome	**Trial arm**	**Prevalance**	**OR (unadjusted)[1]**	**OR (adjusted)[2]**	**OR (adjusted including baseline)[3]**
PCL	Control	271 (11·5%)	1	1	1
	Intervention	432 (10·9%)	0·95 (0·77-1·17)	0·91 (0·74-1·10)	0·92 (0·75-1·14)
PHQ-9 /GAD	Control	150 (6·4%)	1	1	1
	Intervention	246 (6·2%)	0·98 (0·77-1·25)	0·88 (0·69-1·11)	0·91 (0·71-1·16)
Any MH case	Control	296 (12·5%)	1	1	1
	Intervention	492 (12·4%)	1·00 (0·82-1·21)	0·93 (0·77-1·12)	0·95 (0·79-1·16)
AUDIT	Control	288 (12·2%)	1	1	1
	Intervention	462 (11·6%)	0·94 (0·78-1.14)	0·91 (0·76-1·08)	0·88 (0·73-1·06)
SF36 (case = "most of the time/all of the time")	Control	182 (7·8%)	1	1	1
	Intervention	295 (7·6%)	0·96 (0·78-1·19)	0·89 (0·72-1·10)	0·89 (0·72-1·09)
Three or more PCS in those with mTBI	Controls	29 (76.3%)	1	1	
	Intervention	45 (64.3%)	0.56 (0.23- 1.37)	0.53 (0.21- 1.36)	

PCL= posttraumatic stress disorder checklist civilian version; PHQ-9 = Patient Health Questionnaire-9; GAD-7= Generalised Anxiety Disorder-7 Scale; MH= any mental disorder, except alcohol misuse; AUDIT= Alcohol Use Disorder Identification Test; SF-36= Short Form-36. The definitions of caseness are given in the text. PHQ-15 was not included in the baseline questionnaire; PCS= post-concussion symptoms.

[1] Using STATA "xtmelogit" command, with platoon as the nesting variable

[2] Using STATA "xtmelogit" command, including service arm date of deployment, rank and age category as a fixed effect variables, with platoon as the nesting variable

[3] Using STATA "xtmelogit" command, including baseline outcome (any mental health case for PCL and PHQ/GAD), service arm, deployment, rank and age category as fixed effect variables, with platoon as the nesting variable. 529 participants at follow up who were not assessed at baseline were excluded in this analysis.

Table 5 Effect of intervention on help–seeking and pharmaceutical use

Outcome	**Trial arm**	**Number affected (%)**	**Odds ratio (95% CI)**	**Adjusted odds ratio[1] (95% CI)**
Any health visit	Control	1,500 (63·3)	1	1
	Intervention	2,410 (60·3)	0·87 (0·78–0·99)*	0·89 (0·79–1·01)
Medical service usage	Control	1,450 (61·2)	1	1
	Intervention	2,327 (58·2)	0·88 (0·78–0·99)*	0·89 (0·79–1·01)
Welfare service usage	Control	356 (15·0)	1	1
	Intervention	557 (13·9)	0·92 (0·77–1·09)	0·93 (0·79–1·10)
Mental health service usage	Control	318 (13·4)	1	1
	Intervention	496 (12·4)	0·91 (0·78–1·07)	0·92 (0·78–1·08)
Antidepressant usage	Control	67 (2·9)	1	1
	Intervention	129 (3·3)	1·15 (0·81–1·61)	1·08 (0·76–1·54)
Sleeping pill usage	Control	201 (8·6)	1	1
	Intervention	312 (8·0)	0·92 (0·75–1·13)	0·91 (0·74–1·11)

* $p < 0.05$

[1] Adjusted for service, deployment, rank and age category

Table 6: Prevalence and odds ratios in the follow up stage stratifying intervention arm by participant viewing tailored advice

Outcome	**Trial arm**	**Prevalence (%)**	**OR (unadjusted for baseline caseness)**	**OR (adjusted for baseline caseness)[1]**
PCL	Control	247 (11·6)	1	1
	Intervention, did not view advice	125 (10·3)	0·87 (0·67-1·14)	0·95 (0·73-1·24)
	Intervention, viewed advice	283 (11·4)	1·00 (0·80-1·26)	0·91 (0·73-1·14)
PHQ-9 /GAD	Control	138 (6·5)	1	1
	Intervention, did not view advice	66 (5·4)	0·83 (0·60-1·16)	0·89 (0·64-1·23)
	Intervention, viewed advice	162 (6·6)	1·02 (0·78-1·33)	0·91 (0·70-1·19)
Any MH case	Control	271 (12·8)	1	1
	Intervention, did not view advice	139 (11·4)	0·88 (0·69-1·14)	0·96 (0·75-1·23)
	Intervention, viewed advice	324 (13·1)	1·05 (0·85-1·30)	0·95 (0·77-1·17)
AUDIT	Control	265 (12·5)	1	1
	Intervention, did not view advice	143 (11·8)	0·92 (0·73-1·18)	0·96 (0·76-1·22)
	Intervention, viewed advice	298 (12·1)	0·96 (0·78-1·18)	0·84 (0·69-1·02) (p = 0·084)
SF-36	Control	166 (8·0)	1	1
	Intervention, did not view advice	100 (8·5)	1·08 (0·82-1·42)	1·01 (0·77-1·32)

	Intervention, viewed advice	178 (7·3)	0·91 (0·72-1·15)	0·83 (0·66-1·04) (p = 0·10)

PCL= posttraumatic stress disorder checklist civilian version; PHQ-9 = Patient Health Questionnaire-9; GAD-7= Generalised Anxiety Disorder-7 Scakle; MH= Any mental disorder, except alcohol misuse; AUDIT= Alcohol Use Disorder Identification Test; SF-36= Short Form-36. The definitions of caseness are given in the text.

[1] Using STATA "xtmelogit" command, including baseline outcome (any mental health case for PCL and PHQ/GAD), service arm, deployment, rank and age category as fixed effect variables, with platoon as the nesting variable

Table 7 Effect of viewing advice on seeking mental health services and pharmacological usage in the last 12 months

Advice	Trial arm	No. with MH visit (%)	AOR [1](95% CI)	No. using anti-depressants (%)	AOR[1] (95% CI)	No. using hypnotics (%)	AOR[1] (95% CI)
Would have received advice that there was no cause for concern regarding mental health							
Excluding alcohol misuse	Control arm (n = 1,974)	228 (11·6)	1	40 (2·1)	1	151 (7·7)	1
	Viewed advice (n = 2,306)	259 (11·2)	0·94 (0·78–1·14)	64 (2·8)	1·30 (0·84–2·01)	170 (7·5)	0·94 (0·74–1·19)
	Did not view advice (n = 1,152)	130 (11·3)	0·93 (0·74–1·18)	26 (2·3)	1·04 (0·61–1·77)	72 (6·4)	0·79 (0·58–1·06)
Including alcohol misuse	Control arm (n = 1,844)	208 (11·3)	1	38 (2·1)	1	131 (7·2)	1
	Viewed advice (n = 2,120)	228 (10·8)	0·92 (0·75–1·12)	53 (2·5)	1·16 (0·74–1·82)	142 (6·8)	0·92 (0·72–1·19)
	Did not view advice (n = 1,097)	126 (11·5)	0·98 (0·77–1·24)	24 (2·2)	1.01 (0·59–1.72)	67 (6·3)	0·84 (0·62–1·15)
Would have received advice to seek help after a positive result for a mental disorder							
Excluding alcohol misuse	Control arm (n = 148)	53 (35·8)	1	21 (14·2)	1	34 (23·9)	1
	Viewed advice (n = 200)	70 (35·0)	1·06 (0·67–1·67)	27 (13·9)	0·93 (0·49–1·76)	43 (22·2)	1·01 (0·57–1·79)
	Did not view advice (n = 49)	12 (24·5)	0·55 (0·26–1·16)	7 (14·9)	1·12 (0·43–2·90)	16 (34·0)	1·80 (0·80–4·03)
Including alcohol misuse	Control arm (n = 278)	73 (26·3)	1	23 (8·4)	1	54 (19·6)	1
	Viewed advice (n = 386)	101 (26·2)	1·05 (0·73–1·50)	38 (10·0)	1·12 (0·64–1·98)	71 (18·7)	0·92 (0·61–1·39)
	Did not view advice (n = 104)	16 (15·4)	0·50 (0·27–0·92)*	9 (8·9)	1·05 (0·45–2·44)	21 (20·8)	1·02 (0·56–1·83)

[1] Adjusted for service, deployment, rank and age category

Research in context

Evidence before this study

On completion of the study in January 2016, we carried out search of Medline, Embase and Psychoinfo to identify any studies on post-deployment screening with the terms "mental disorders", "psychological illness", "mental health", "posttraumatic stress disorder", "PTSD", "depression", "anxiety"," alcohol misuse", or "alcoholism", and "post-deployment", "screening", and "RCT", "randomised controlled trial" or" effectiveness" which yielded 11 publications, five of them duplicates, none of them relevant to the aim of this study. We changed the term "post-deployment" for "military", "armed forces", "army", "navy", or "air force" to make it less restrictive. The search provided 68 publications, 16 duplicates, none of which were considered relevant to our study. A similar search, including one of the terms '"help-seeking", "treatment seeking", "health service provision" or "service use",' was carried out for the effects on help-seeking in April 2016. There were only 2 papers fulfilling these search criteria, neither of which were relevant to this study. Post-deployment screening for mental disorders was not a consideration in the military until after the Gulf War in 1991. Post-deployment screening for mental disorders was mandated by the US Congress in 1998 and since 2003, screening was implemented among US forces and developed and modified during the Iraq and Afghanistan conflicts.

Added value of this study

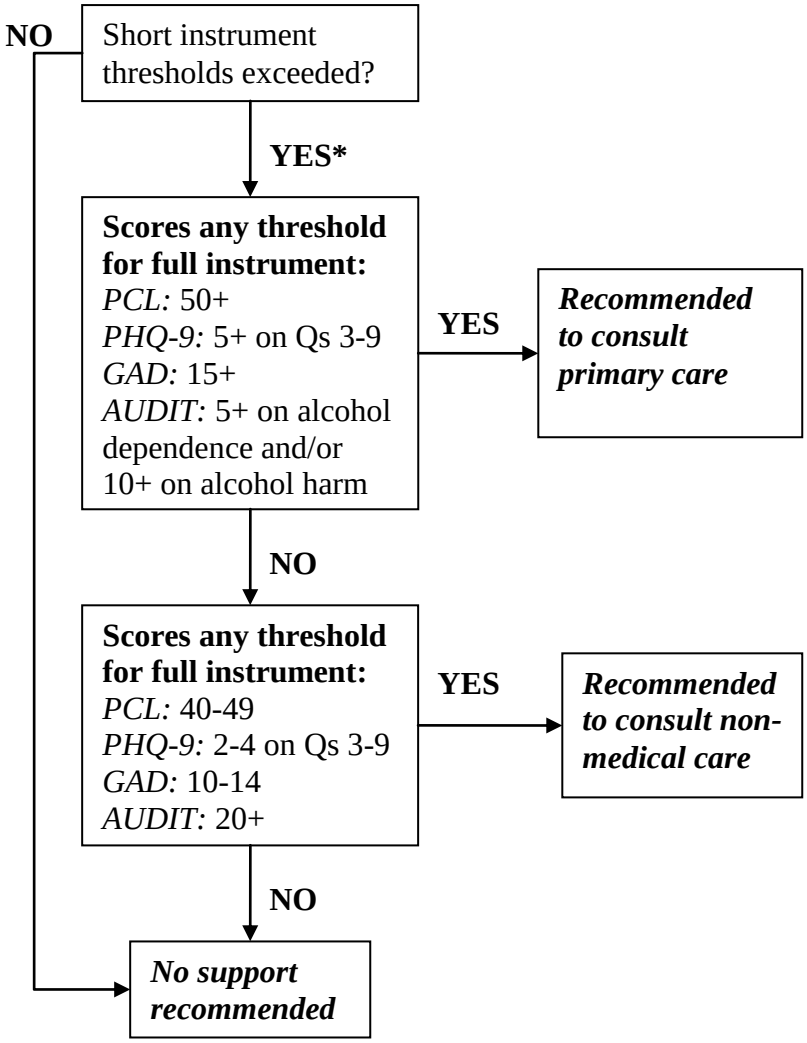
This is the only RCT study of post-deployment screening for mental disorders that has been carried out. The US, Canada, Australia and Holland have implemented post-deployment screening already and are unable to carry out an RCT without ceasing their current programme which is politically impossible in those countries. The conditions explored in our study are those usually assessed in any screening programmes for mental disorders. The results of our study should help to develop or modify models of post-deployment screening programmes implemented in countries where screening is mandatory. Armed Forces which are considering the introduction of a post-deployment

screening could benefit from the findings of our study. It should be also helpful to occupations facing high risk of exposure to trauma such as emergency services and media.

Implications of all the available evidence

Our study demonstrated that post-deployment screening based on tailored advice is not effective in reducing the prevalence of mental disorders. This is consistent with the finding that tailored advice does not increase help-seeking. This is not entirely surprising given the well-known findings that in most studies that around half of those with a mental disorder do not seek health-care, that many of those who seek health care do not go beyond the initial assessment and that a large percentage who initiate treatment do not finish it. Our study demonstrated that as many as a third of those who were given the opportunity to receive tailored advice chose not to see it. Of course, screening programmes and procedures will vary between countries. It is for each country to assess whether differences in detail between their programmes and our study could make a difference to the results presented here. At the very least, countries which have implemented post-deployment screening should have a monitoring system in place to evaluate the psychological and financial impact of their programmes.

Figure 1 Decision pathway related to the intervention arm of the trial. Control arm received the same assessment but only general advice (see text).

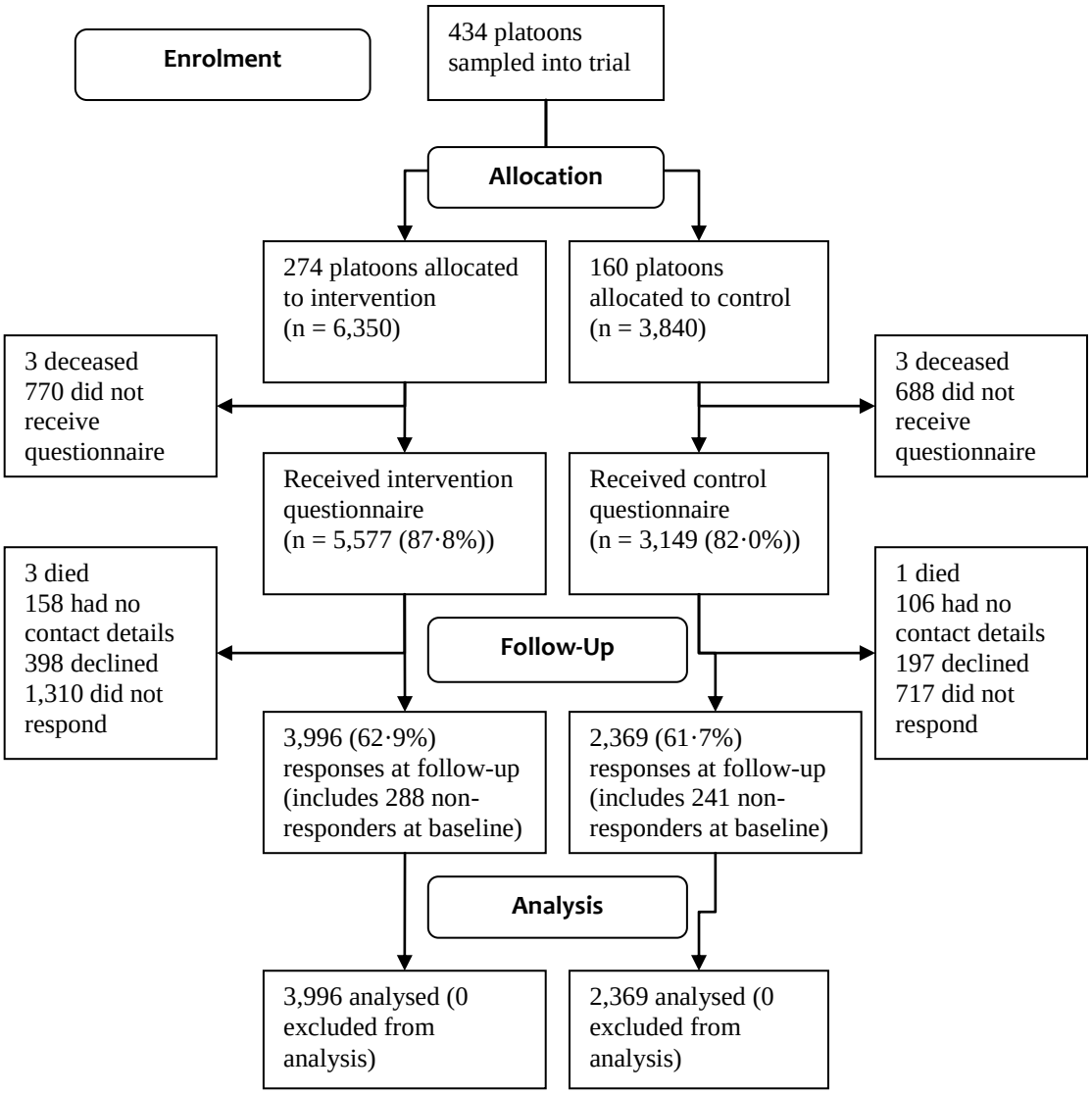


PCL= Posttraumatic stress disorder Checklist = Civilian version; PGQ-9= Patient Health Questionnaire-9; GAD= Generalised Anxiety Disorder; AUDIT= Alcohol Use Disorder Identification Test

* Respondents only directed to full instruments for which they fulfilled the threshold on the short instrument

Figure 2

Figure 2 Participants, percentage rates and numbers leaving the study at each stage by arm of the trial. Percentages estimated from total service personnel in each arm at enrolment



Supplementary Material

Click here to download Supplementary Material: LancetSupplementaryMaterial(010916).docx

Supplementary Tables 1 and 2

Click here to download Supplementary Material: LancetSupplementTable 1,2 (060716)Final.docx

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Yes
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Yes
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Yes
	2b	Specific objectives or hypotheses	Yes
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Yes
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Yes
Participants	4a	Eligibility criteria for participants	Yes
	4b	Settings and locations where the data were collected	Yes
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Yes
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Yes
	6b	Any changes to trial outcomes after the trial commenced, with reasons	None
Sample size	7a	How sample size was determined	Yes
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Yes
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Yes
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Yes
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Yes
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Yes
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Yes

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Not necessary
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Yes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Yes
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Yes
	13b	For each group, losses and exclusions after randomisation, together with reasons	Yes
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Yes
	14b	Why the trial ended or was stopped	Not necessary
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Yes
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Only primary outcomes
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not necessary
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Yes
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Yes
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Yes
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Yes
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Yes
Other information			
Registration	23	Registration number and name of trial registry	Yes
Protocol	24	Where the full trial protocol can be accessed, if available	Submitted to the Lancet
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.